

AMENDMENTS TO THE DRAWINGS

The attached sheets of drawings includes changes to FIGS 1-7.

Attachment: Replacement sheets 1-4

REMARKS

Formal drawings as requested in the Office Action are enclosed herewith. Please replace the previously filed drawings with the enclosed formal drawings.

Claims 1-42 had been presented. Claims 1-42 were rejected for the reasons detailed below. Claims 6-12, 19, 22-25 have been cancelled. Claims 1, 20-21, 26, and 32, have been amended. Claims 43-56 have been added. After the amendments and cancellations, claims 1-5, 13-18, 20-21, 26-56 are pending. Applicant respectfully requests reconsideration.

Claim Objections

Claims 26 and 32 were objected to because the Examiner believed Applicant had mistakenly recited the relative elasticity of outer and inner layers. Claims 26 and 32 have been amended to recite that the elasticity of the outer layer is greater than the elasticity of the inner layer.

Rejection under 35 U.S.C. § 102(b)

Claims 1-6, 12-16, 19-23, 32, 37-39, and 42 were rejected under 35 U.S.C. § 102(b) as allegedly unpatentable over U.S. Patent No. 5,318,588 to Horzewski et al. (herein "Horzewski"). Claims 6, 12, 19, 22-23 have been cancelled; therefore, the rejections of those claims are moot. Applicant disagrees with the remaining rejections.

Claim 1 recites a device comprising a conduit for insertion into a living body, and through which another device passes. The conduit has inner and outer coaxial layers bonded together such that the outer layer surrounds the inner layer. The durometer of the inner layer is greater than the durometer of the outer layer, and the circumference of the inner layer is discontinuous and non-overlapping.

Horzewski does not teach or suggest the recited combination of amended claim 1. In fact, as the Office Action states, the inner layer of Horzewski has an overlapping portion to help expand the inner layer.

Thus, Applicant respectfully traverses these rejections as Horzewski does not teach or suggest all of the limitations of claim 1. Specifically, Horzewski lacks an inner layer with a circumference that is discontinuous and non-overlapping, as required by amended claim 1. As mentioned above, Horzewski teaches an overlapping inner layer. See Horzewski col. 9, line 62 – col. 10, line 24.

Claim 2 depends from claim 1 and further recites that the conduit is an introducer sheath. Claim 3 depends from claim 1 and further recites that the conduit is a catheter. Claim 4 depends from claim 1 and further recites that the inner layer has means for assisting the diameter of the inner layer to expand. Claim 5 depends from claim 4 and further recites that the assisting means includes a slit formed longitudinally in the inner layer. As claims 2-5 also include the combination recited in claim 1, claims 2-5 are patentable over the cited reference for at least the same reasons as claim 1.

Claim 13 depends from claim 1 and further recites that the inner layer has a durometer in a range of 60-80 on the D scale. Claim 14 depends from claim 13 and further recites that the outer layer has a durometer in a range of 20-70 on the A scale. Claim 15 depends from claim 1 and further recites that the outer layer has a durometer in a range of 20-70 on the A scale. Claim 16 depends from claim 1 and recites that the device further comprises a medical device for insertion through the conduit. The medical device has a portion with an outer diameter greater than the inner diameter of the inner layer. The conduit expands temporarily and radially as the medical device is passed through. As claims 13-16 also include the combination recited in claim 1, claims 13-16 are patentable over the cited reference for at least the same reasons as claim 1.

Claims 20 and 21 now depend from claim 38. The rejections of these claims is addressed below.

Claim 32 recites a method comprising providing a medical device through a conduit in a living body. The conduit has inner and outer coaxial layers bonded together such that the outer layer surrounds the inner layer. The elasticity of the outer layer is greater than the elasticity of the inner layer and the circumference of the inner layer is discontinuous and non-

overlapping. The conduit temporarily expands in the radial direction as the device passes through.

Horzewski does not teach or suggest the recited combination of amended claim 32. As mentioned above, the inner layer of Horzewski has an overlapping portion to help expand the inner layer.

Thus, Applicant respectfully traverses these rejections as Horzewski does not teach or suggest all of the limitations of claim 32. Specifically, Horzewski lacks an inner layer with a circumference that is discontinuous and non-overlapping, as required by amended claim 32.

Claim 37 depends from claim 32 and further recites that the inner layer has means for assisting the inner layer to expand radially. As claim 37 also includes the combination recited in claim 32, claim 37 is patentable over the cited reference for at least the same reasons as claim 32.

Claim 38 recites a device comprising a conduit for insertion into a living body, and through which another device passes. The conduit has first and second types of sections in a circumferential direction. The elasticity of one type of section is greater than the elasticity of the other type of section. The different elastic sections allow the conduit to expand temporarily in the radial direction.

Horzewski does not teach or suggest the recited combination of amended claim 38. The Office Action states that Horzewski teaches a conduit with two layers bonded together wherein the inner layer has a higher durometer than the outer layer. Indeed, Horzewski states that the shaft of the device contains at least two layers, an inner relatively inelastic layer and an outer relatively elastic layer. See Horzewski at col. 7, lines 38-40.

Thus, Applicant respectfully traverses these rejections as Horzewski does not teach or suggest all of the limitations of claim 38. Specifically, Horzewski lacks first and second types of sections in a circumferential direction wherein the elasticity of one type of section is greater than the elasticity of the other type of section, as required by claim 38.

Claim 20 now depends from claim 38 and further recites that the conduit is an introducer sheath. Claim 21 now depends from claim 38 and further recites that the conduit is a catheter. Claim 39 depends from claim 38 and recites that the device further comprises a medical device for insertion through the conduit. The medical device has a portion with an outer diameter greater than the inner diameter of the inner layer. The conduit expands temporarily and radially as the medical device is passed through. Claim 42 depends from claim 38 and further recites that the conduit has a substantially uniform wall thickness. As claims 20-21, 39, and 42 also include the combination recited in claim 38, claims 20-21, 39, and 42 are patentable over the cited reference for at least the same reasons as claim 38.

Rejections under 35 U.S.C. § 103(a)

Claims 7-11, 17-18, 24-25, 33-36, and 40-41 were rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Horzewski. Claims 7-11 and 24-25 have been cancelled; therefore, the rejections of those claim are moot. Applicant disagrees with the remaining rejections.

Claim 17 depends from claim 16, which depends from claim 1, discussed above, and further recites that the medical device is selected from the group consisting of a stent, blood clot filter, or occluder. Claim 18 depends from claim 1 and recites that the device further comprises a medical device for passing through the conduit. The medical device is foldable in a first manner for delivery through the conduit and in a second manner different from the first manner for retrieval. The cross-section of the device as folded in the second manner is greater than the cross-section of the device as folded in the first manner. The device as folded in the first manner has an outer diameter less than the inner diameter of the conduit, and the device as folded in the second manner has an outer diameter greater than the inner diameter of the conduit. The conduit does not expand as the device is delivered and expands temporarily and radially as the medical device is retrieved. As claims 17 and 18 also include the combination recited in claim 1, claims 17 and 18 are patentable over the cited reference for at least the same reasons as claim 1.

Claim 33 depends from claim 32, discussed above, and further recites that the medical device has an outer diameter greater than the inner diameter of the inner layer. Claim 34 depends from claim 33 and further recites that the outer diameter of the device is greater when it is delivered. Claim 35 depends from claim 33 and further recites that the outer diameter of the device is greater when it is retrieved, but not when it is delivered. Claim 36 depends from claim 32 and further recites that the medical device is selected from the group consisting of a stent, blood clot filter, or occluder. As claims 33-36 also include the combination recited in claim 32, claims 33-36 are patentable over the cited reference for at least the same reasons as claim 32.

Claim 40 depends from claim 39, which depends from claim 38, discussed above, and further recites that the medical device is selected from the group consisting of a stent, blood clot filter, or occluder. Claim 41 depends from claim 38 and recites that the device further comprises a medical device for passing through the conduit. The medical device is foldable in a first manner for delivery through the conduit and in a second manner different from the first manner for retrieval. The cross-section of the device as folded in the second manner is greater than the cross-section of the device as folded in the first manner. The device as folded in the first manner has an outer diameter less than the inner diameter of the conduit, and the device as folded in the second manner has an outer diameter greater than the inner diameter of the conduit. The conduit does not expand as the device is delivered and expands temporarily and radially as the medical device is retrieved. As claims 40 and 41 also include the combination recited in claim 38, claims 40 and 41 are patentable over the cited reference for at least the same reasons as claim 38.

Claims 26-31 were rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Horzewski in view of U.S. Patent No. 5,944,691 (herein "Querns"). Applicant disagrees with the rejections.

Claim 26 recites a method comprising forming one of an introducer sheath or catheter through which a medical device is passed with inner and outer coaxial layers bonded together such that the outer layer surrounds the inner layer. The elasticity of the outer layer is greater

than the elasticity of the inner layer. Furthermore, the circumference of the inner layer is discontinuous and non-overlapping

Neither the references alone, nor in combination, teach or suggest the recited combination of amended claim 26. Even if the references did teach the required combination, a person having ordinary skill in the art and employing ordinary creativity would not be motivated to make the combination suggested by the Examiner.

Thus, Applicant respectfully traverses these rejections as the Office Action does not present a *prima facie* case for obviousness based upon the teachings of Horzewski in view of Querns because these references do not teach or suggest all of the limitations of claim 26. Specifically, the Examiner's proposed combination lacks an inner layer with a circumference that is discontinuous and non-overlapping, as required by amended claim 26.

Furthermore, as explained below, a person having ordinary skill in the art and employing ordinary creativity would not be motivated to make the combination suggested by the Examiner. As explained above, the Examiner admits Horzewski teaches a conduit with an inner layer that has an overlapping portion. Meanwhile, Querns is directed to a single layer catheter and does not teach or suggest inner and/or outer layers at all. For at least these reasons, a person having ordinary skill in the art would not make the combination suggested by the Examiner. Therefore, the Examiner has failed to establish a *prima facie* case of obviousness with regard to claim 26.

Claim 27 depends from claim 26 and further recites that the layers are bonded together through co-extrusion. Claim 28 depends from claim 26 and further recites that the layers are bonded together through dipping. Claim 29 depends from claim 26 and further recites forming the inner layer with means for allowing the diameter of the inner layer to expand. Claim 30 depends from claim 26 and further recites that the forming includes forming an introducer sheath. Claim 31 depends from claim 26 and further recites that the forming includes forming a catheter. As claims 27-31 also include the combination recited in claim 26, claims 27-31 are patentable over the cited references for at least the same reasons as claim 26.

In view of the foregoing remarks, Applicant submits that all pending claims are in condition for allowance, which action is earnestly solicited.

Applicant respectfully requests an early and favorable reconsideration and issuance of this application as amended herein. The Examiner is encouraged to contact the undersigned to expedite prosecution of this application.

An authorization to charge the new claims fees of \$150 to our Deposit Account No. 08-0219 for new claims 43-56 accompanies this response. No other fees are believed to be due in connection with this submission. However, if any fees are due in connection with this application, please charge them to our Deposit Account No. 08-0219.

Respectfully submitted,

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Attachments – Formal Drawings

REPLACEMENT SHEETS

Formal drawings follow this page.